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THOMAS Q. HENRY  
WOODARD EMHARDT NAUGHTON & MCNETT  
111 MONUMENT CIRCLE  
SUITE 3700  
INDIANAPOLIS, IN 46204

EXAMINER

LEWIS, KIM M

ART UNIT

PAPER NUMBER

3761

DATE MAILED: 04/11/2003

25

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

08/894,548

Applicant(s)

QIN ET AL.

Examiner

Kim M. Lewis

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 24 August 2001.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 20-22, 24, 25, 28-39, 41-44, 46 and 47 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 20-22, 24, 25, 28-39, 41-44, 46 and 47 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☒ Other: *Detailed Action*.

## **DETAILED ACTION**

### ***Response to Amendment***

1. The after final amendment filed on 8/21/01 has been received and made of record. The amendments made therein have been entered. Specifically, claims 19, 27, 40 and 45 have been cancelled. Claims 20-25, 28-39 and 41-44 have been amended.

Additionally, the finality of the office action of paper no. 18, mailed 8/24/01 has been withdrawn, and prosecution on this application has been reopened since the examiner neglected to reject claim 47 therein.

### ***Claim Objections***

2. Applicant is advised that should claim 38 be found allowable, claim 42 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

### ***Claim Rejections - 35 USC § 112***

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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4. Claims 35 and 42-44 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

As regards claim 35, "the adhesive" lacks proper antecedent basis.

As regards claims 42-44, "said layer (i)" lacks proper antecedent basis.

***Claim Rejections - 35 USC § 103***

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

7. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was

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not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

8. Claims 47, 21-25, 29-33, 36, 37, 41-44 and 46 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,830,496 ("Freeman") in view of U.S. Patent No. 5,782,787 ("Webster").

As regards claim 47, Freeman discloses a wound dressing (Fig. 3) comprising a first wound contact layer (11) including an alginate and constructed from a non-woven material (col. 3, lines 35-38 and lines 59-63) and a second non-woven layer (12) of greater hydrophilicity since it contains a superabsorbent (col. 5, lines 4-9 and 15-18).

Freeman additionally discloses a top or outer surface layer constructed from a porous stretchable material. Freeman fails to teach that the outer surface layer is a film layer. However, Webster teaches it is conventional in the art to place a porous stretchable film layer over an absorbent layer for the purpose of regulating water vapor loss from the wound area beneath the dressing.

It would have been an obvious design choice to one having ordinary skill in the art to substitute the porous stretchable layer of Freeman for the porous stretchable film layer of Webster since they perform the same function of regulating water vapor loss from the wound area. Such a substitution results in an **equivalent exchange** of one breathable, stretchable layer for another.

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As regards claim 21, Freeman discloses that layer (i) may be a non-woven layer and that layer (ii) is constructed from superabsorbents. As such, layer (ii) has greater hydrophilicity than layer (i).

Freeman fails to teach that layer (ii) has twice the hydrophilicity as that of layer (i). Since Freeman provides several methods of incorporating the superabsorbent material into layer (ii) (col. 5-col. 6), the examiner contends that the manner in which the superabsorbent material is applied to layer (ii) affects the hydrophilicity of that layer. As such, depending upon the required hydrophilicity of layer (ii), one having ordinary skill in the art would select one method of incorporation of the superabsorbent over another as an obvious design choice.

It then follows that the hydrophilicity of each layer is an obvious design choice based upon the selected materials for each layer and the method by which the superabsorbents are incorporated into layer (ii).

As regards claims 22, 28, 29, 32 and 36, Freeman and Webster disclose the claimed invention except for the particulars of the thickness of the layers, the choice of material, and the MVTR as claimed in claims 22, 28, 29, 32 and 36. It would have been an obvious matter of design choice to add these particulars to the modified device of Freeman since the applicant has not disclosed that the particulars solve any stated problem or are for any particular purpose, and it appears that the invention would perform equally well with different thicknesses, MVTR values, and materials.

Whether these particulars solve any particular problem or produce any unexpected result, I must conclude that they are merely matters of engineering design

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choice, and thus do not serve to patentably distinguish the claimed invention over the prior art. *In re Kuhle*, 526 F.2d 53, 188 USPQ 7 (CCPA 1975).

Applicant is also reminded that arguments toward the criticality of an element will generally be given little patentable weight. The basis for criticality should be disclosed in the specification or supplied by affidavit. *In re Cole*, 140 USPQ 230 (CCPA) 1964).

As regards claim 24, the examiner contends that the first layer of Freeman is **capable** of debridement.

As regards claim 25, note col. 3, lines 59-64 of Freeman, which discloses that alginate is delivered to the wound.

As regards claim 30 and 31, note col. 5, lines 36-48 of Webster, which discloses the MVTRs.

As regards claim 33, note col. 5, lines 46-48 of Freeman, which discloses the use of polyurethane.

As regards claims 37 and 42, Freeman discloses the use of calcium alginate (col. 3, line 63).

As regards claims 41 and 46, both Freeman and Webster fail to teach that the wound contacting layer comprises felt. Absent a critical teaching and/or a showing of unexpected results derived from the use of felt in the wound contacting layer, the examiner contends that the use of felt is an obvious design choice, which does not patentably distinguish applicant's invention.

As regards claims 43 and 44, both Freeman and Webster fail to disclose that the wound contacting layer comprises zinc alginate or silver alginate. However, since

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Freeman discloses the use of calcium alginate and sodium alginate, the examiner contends that the addition of an equivalent alginate, namely, zinc alginate or silver alginate, both of which are conventionally known for their wound healing effects, would have been *prima facie* obvious to one having ordinary skill in the art.

9. Claims 34 and 35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Freeman in view of Webster as applied to claim 47 above, and in further view of U.S. Patent No. 5,632,731 ("Patel").

As regards claims 34 and 35, Freeman and Webster fail to teach adhesive provided on the film for bonding to the skin. However, Patel teaches it is known to provide wound dressings having film layers with a hydrocolloid (hydroactive) adhesive thereon for the purpose of bonding the dressing to the user's skin and absorbing wound exudate.

It would have been obvious to one having ordinary skill in the art to provide the modified dressing of Freeman with a hydrocolloid (hydroactive) adhesive layer for purposes of bonding to the wound dressing to the user's skin and absorbing wound exudates.

10. Claim 38 is rejected under 35 U.S.C. 103(a) as being unpatentable over Freeman in view of Webster as applied to claim 47 above, and in further view of U.S. Patent No. 4,363,319 ("Altshuler").



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As regards claim 38, both Freeman and Webster fail to teach the wound contact layer is comprised of a material, which promotes clotting via agglutination. However, the examiner contends that the addition of any medicament to the wound contact layer for treatment of the wound would have been *prima facie* obvious to one having ordinary skill in the art.

Additionally, the applicant should note that Altshuler teaches it is conventionally known to provide bandages with material that promotes clotting via agglutination (e.g. thrombin).

In view of Altshuler, it would have been obvious to one having ordinary skill in the art to provide the modified dressing of Freeman with blood clotting material in order to stop bleeding.

11. Claim 39 is rejected under 35 U.S.C. 103(a) as being unpatentable over Freeman in view of Webster as applied to claim 47 above, and further in view of U.S. Patent No. 4,960,413 ("Sagar et al.").

As regards claim 39, both Freeman and Webster fail to teach the use of chitosan. However, Sagar et al. teach it is conventional to provide wound dressings with chitosan for its wound healing properties.

In view of Sagar et al., it would have been obvious to one having ordinary skill in the art to provide the modified dressing of Freeman with chitosan for its wound healing properties.

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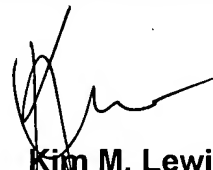
***Response to Arguments***

12. Applicant's arguments with respect to the claims have been considered but are moot in view of the new ground(s) of rejection.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kim M. Lewis whose telephone number is 703.308.1191. The examiner can normally be reached on Mondays and Tuesdays from 6:30 am to 3:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Weilun Lo can be reached on 703.308.1957. The fax phone numbers for the organization where this application or proceeding is assigned are 703.305.3590 for regular communications and 703.305.3590 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703.308.0858.



**Kim M. Lewis  
Primary Examiner  
Art Unit 3761**

kml  
March 31, 2003